

Remarks

Claims 14 and 19 have been amended. The amendments to claim 14 insert the structural formula for melagatran (see, *e.g.*, paragraph [0014] of Applicant's published application for representative support); replace the term "derivative" with salts, solvates or prodrugs of melagatran (see, *e.g.*, paragraph [0022] of Applicant's published application for representative support); and identify melagatran as active agent that lowers cholesterol (see, *e.g.*, paragraphs [0017] and [0040] of Applicant's published application for representative support). The amendment to claim 19 more clearly identifies the recited prodrug. Applicant submits that no prohibited new matter has been introduced by the amendments.

1. Rejection under 35 U.S.C. 103(a)

Claims 14, 16 and 18 to 21 are rejected as allegedly obvious over US 2004/0067995 to Wong *et al.* ("Wong") for the reasons asserted on pages 2-3 of the Office Action. The Examiner points to paragraph 75 and claim 6 of Wong for teaching that melagatran prodrugs were "known to be administered in combination with other agents for antithromboembolic agents (wherein the other agents that may also be used in combination included cholesterol lowering drugs)." According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of Applicant's claimed invention to use melagatran or any known prodrug thereof in a method for lowering cholesterol.

Applicant submits that Wong does not teach or suggest the administration of melagatran as a means for lowering cholesterol. Instead, Wong discloses compositions comprising a combination of Compound A (a compound structurally unrelated to melagatran containing imidazole-, pyrazole-, and benzisoxazole- moieties) and Clopidogrel (also a compound structurally unrelated to melagatran that is P₂Y₁₂ antagonist with antiplatelet properties). While a third therapeutic agent may be included in these Compound A-Clopidogrel combination compositions, the agent is broadly described as being selected from, *e.g.*, other anti-coagulant or coagulation inhibitory agents, anti-platelet or platelet inhibitory agents, thrombin inhibitors, thrombolytic agents, fibrinolytic agents, anti-arrhythmic agents and cholesterol/lipid lowering

agents. Aspirin and pravastatin (neither of which is a thrombin inhibitor) are listed as the preferred choices for the third agent (see, *e.g.*, paragraph [0028], Example 4 and Figure 4 of Wong).

Melagatran is only mentioned in Wong in paragraph [0075], where it is described as one of a group of known thrombin inhibitors. At no point is it indicated in Wong that melagatran has the potential to act as a cholesterol-lowering agent. In fact, the phrase “cholesterol lowering agent” is defined in Wong at paragraph [0078] as including a range of substances, none of which is melagatran or its prodrugs. In contrast, Applicant’s claim 14, as amended, identifies melagatran or its salt, solvate or prodrug thereof as a cholesterol-lowering agent in the claimed therapy method. While melagatran may possibly be present as a third agent in a composition described in Wong, there is no suggestion that melagatran (or any of its salts, solvates or prodrugs thereof) is, or could function as, a cholesterol-lowering agent. A person of ordinary skill in the art after reading Wong would therefore have no rationale, even less a reasonable expectation of success, in using melagatran or a salt, solvate or prodrug thereof, in a cholesterol-lowering therapy method where the melagatran is the agent responsible for lowering cholesterol. Applicant respectfully requests withdrawal of this rejection.

2. Rejection under 35 U.S.C. 112, first paragraph

Claims 14, 16 and 19-21 are rejected for allegedly failing to comply with the written description requirement due to the recitation of the term “derivative”.

Without acquiescing to the merits of the Examiner’s rejection, Applicant has amended claim 14 to replace the term “derivative” with “salt, solvate or prodrug”. Applicant submits that this amendment is fully supported by the specification at, *inter alia*, paragraph [0022] of Applicant’s published application. In view of the removal of the contested term, Applicant respectfully requests withdrawal of this rejection.

*

3. **Rejection under 35 U.S.C. 112, second paragraph**

Claims 18-21 are rejected as allegedly indefinite due to the recitation of the term “prodrug” in claim 18. The Examiner asserts that the term finds no antecedent basis, as claim 14 does not recite the term.

Without acquiescing to the merit of the Examiner’s rejection, Applicant has amended claim 14 to replace the term “derivative” with “salt, solvate or prodrug”. Accordingly, claim 14 now explicitly recites the term “prodrug”. Applicant respectfully requests that this rejection be withdrawn.


4. **Conclusion**

The foregoing amendments and remarks are made to place the application in a condition for allowance. Applicant respectfully requests reconsideration and the timely allowance of the pending claims. The Examiner is invited to telephone the undersigned to advance prosecution of the application.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **January 22, 2009**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel.: 202-739-3000
Fax: 202-739-3001

Respectfully submitted,
Morgan, Lewis & Bockius LLP



Gregory T. Lowen
Registration No. 46,882
Direct: 202-739-5915